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Docket No.	:	75329.77432	

Via Electronic Filing

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

AMENDMENT IN RESPONSE TO NON-FINAL OFFICE ACTION

This paper is filed in response to the Office Action mailed June 28, 2006. Applicant acknowledges with appreciation the allowance of claims 58-94 and withdrawal of the rejection previously asserted under 35 U.S.C. §102(a). Applicant hereby requests entry of these amendments and reconsideration and withdrawal of the objections to the specification and claims, and of the rejection under 35 U.S.C. §103(a), in view of the amendments and remarks presented below. No additional fee is required for filing this response.

Applicant also notes that the application title appearing in the heading above has been revised from that appearing on amendments and papers previously filed in view of realization by the undersigned while preparing this amendment that the title was previously amended by prior counsel to "A Retractable Syringe Assembly Designed for One Use" in the Preliminary Amendment filed July 17, 2000. On the Official Filing Receipt mailed September 22, 2000, the introductory "A" was dropped from the title, and the title was restated as Retractable Syringe Assembly Designed for One Use, which appears in the heading of this paper. Because this revision reflects an amendment previously made, it is not presented in the Amendments to the Specification section that follows.

Amendments to the Specification begin at page 3.

Amendments to the Claims begin at page 4.

Remarks begin at page 23.

Amendments to the Specification

Please amend the Cross Reference to Related Applications as follows:

This is a continuation of copending patent application serial number 08/843,050 filed April 25, 1997 entitled "Syringe Plunger Handle Assembly and Barrel, now U.S. 6,090,077, which was a continuation-in-part of patent application serial number 08/537,242 filed September 29, 1995 entitled "Tamperproof Retractable Syringe", now U.S. Patent 5,632,733, which in turn was a continuation-in-part of patent application serial number 08/438,954 filed May 11, 1995, now U.S. Patent 5,578,011, all by the same inventor, for which benefit of 35 U.S.C. § 120 is claimed.

Please amend the paragraph beginning at page 9, line 20, as follows:

Manufacture and assembly is facilitated by the fact that the plunger and the outer body can be molded with a non-collapsible core tool that can be pulled out from behind. The parts are simply shaped and do not have hooks and parts with reentrant angles that require collapsible core pin technology. The outer body can be made in one piece and assembled from the rear. The narrowed nose portion provides no lateral space ~~with~~ that will permit bunching of the spring and jamming when the retraction assembly is moved forward in the outer body. In fact, the nose serves as a guide to steer the parts into the proper position in one smooth stroke.

Amendments to the Claims

Claims 1-28 **(canceled)**

29. (currently amended): A syringe assembly having a retractable needle and designed for one-time use, comprising:

a hollow syringe body comprising a barrel having a front end portion containing a retraction mechanism having a retractable needle, a needle holder having an inner head and a continuous retaining member configured for operation by forward movement of a plunger, and a back end portion having an opening;

the continuous retaining member surrounding the inner head of the needle holder and having ~~one~~ a surface mating with a facing surface of the hollow syringe body, thereby making a seal for a variable fluid chamber in the barrel;

a plunger having a front end portion comprising a head, an outer wall ~~a supporting~~ surface on the plunger front end portion having a plunger seal element fixed on the ~~supporting~~ outer wall surface, and a back end portion with an end cap having an outer periphery;

the plunger being reciprocally mounted in said barrel with the plunger seal element in sliding sealed contact with the barrel; and

the ~~retractable needle~~ retraction mechanism being released for retraction of the retractable needle when the plunger is moved forward to release the continuous retaining member, without ~~contact between the plunger seal element and the continuous retaining member and without relative movement between~~ moving the

plunger seal element ~~and its supporting~~ longitudinally along the outer wall surface by contact between the plunger seal element and the continuous retaining member.

the outer periphery of the plunger end cap being receivable into the opening in the back end portion of the hollow syringe body upon retraction.

30. (original): The assembly of claim 29 wherein a structure mounted in the front end portion of the barrel prevents forward motion of the retractable needle during retraction of the needle to prevent pain when the needle is retracted from a patient.

31. (previously presented): The assembly of claim 29 wherein the plunger carries a tip which protrudes to contact the continuous retaining member and release the retractable needle when retraction is initiated by pushing on the plunger.

32. (original): The assembly of claim 29 wherein the continuous retaining member is a separable part of the retraction mechanism which acts as a fluid seal for a variable chamber in the barrel behind the separable part.

33. (currently amended): The assembly of claim 31 wherein the continuous retaining member is separable from the ~~retractable~~ inner head of the needle holder when retraction is initiated by pushing on the plunger.

34. (currently amended): The assembly of claim 33 wherein the continuous retaining member is separated from the ~~retractable~~ inner head of the needle holder by means of force applied by said tip to said continuous retaining member when retraction is initiated by pushing on said plunger.

35. (canceled)

36. (previously presented): The assembly of claim 29 wherein the outer periphery of the plunger end cap is lodged in the opening of the back end portion of the hollow syringe body by pressing the end cap to cause retraction, whereby the plunger cannot be grasped after retraction.

37. (currently amended): A syringe assembly having a retractable needle and designed for one-time use, comprising:

a hollow syringe body comprising a barrel having a front end portion in which a retraction mechanism is mounted, the retraction mechanism having a retractable needle and a continuous retaining member which ~~holds~~ retains the retractable needle prior to retraction, and a back end portion having an opening;

a plunger having a front end portion comprising a head and ~~a supporting~~ an outer wall surface located on the front end portion, with a plunger seal element fixed on the ~~supporting~~ outer wall surface, and a back end portion with an end cap having an

outer periphery, the retraction mechanism being operable by forward movement of the plunger without distorting the barrel;

the plunger being reciprocally mounted in said barrel with the plunger seal element in sliding sealed contact with the barrel; whereby

forward movement of the plunger releases the retractable needle from the continuous retaining member by applying a separating force to the continuous retaining member, without the aid of the plunger seal element and without ~~relative movement between~~ moving the plunger seal element ~~and its supporting~~ longitudinally along the outer wall surface;

the outer periphery of the plunger end cap being receivable into the opening in the back end portion of the hollow syringe body upon retraction.

38. (previously presented): The assembly of claim 37 wherein the continuous retaining member acts as a fixed seal for a variable chamber in the barrel behind the continuous retaining member.

39. (currently amended): The assembly of claim 38 wherein a structure mounted in the front end portion of the barrel prevents forward motion of the retractable needle during retraction of the retractable needle to prevent pain when the retractable needle is retracted from a patient.

40. (currently amended): The assembly of claim 37 wherein the continuous retaining member ~~is separable from~~ releases the retractable needle when retraction is initiated by pushing the plunger to move it forward with respect to the barrel.

41. (previously presented): The assembly of claim 40 wherein the plunger carries a tip which protrudes to contact the continuous retaining member and release the retractable needle when retraction is initiated by pushing on the plunger.

42. (currently amended): The assembly of claim 41 wherein the continuous retaining member ~~is separated from~~ releases the retractable needle by means of force applied by said tip to said continuous retaining member when retraction is initiated by pushing on said plunger.

43. (canceled)

44. (previously presented): The assembly of claim 37 wherein the outer periphery of the plunger end cap is lodged in the opening of the back end portion of the hollow syringe body by pressing the end cap to cause retraction, whereby the plunger cannot be grasped after retraction.

45. (currently amended): A syringe assembly ~~having a retractable needle and~~ designed for one-time use, comprising:

a hollow syringe body comprising a barrel having a front end portion in which a retraction mechanism is mounted, the retraction mechanism having a retractable needle ~~which is~~, a continuous retaining member that retains the retractable needle prior to retraction, and a back end portion having an opening;

the continuous retaining member having ~~one mating~~ a surface mating with a facing surface of the hollow syringe body, thereby making a seal for a variable fluid chamber in the barrel;

a plunger having a front end portion comprising a head and ~~a supporting~~ an outer wall surface located on the front end portion, a plunger seal element fixed on the ~~supporting~~ outer wall surface, and a back end portion having an outer periphery;

the plunger being reciprocally mounted in said barrel with the plunger seal element in sliding sealed contact with the barrel; and

the ~~retractable needle~~ retraction mechanism being released for retraction when the plunger is moved forward to release the continuous retaining member, without the plunger seal element going beyond said ~~one~~ outside ~~mating~~ surface of the continuous retaining member and without ~~motion of~~ moving the plunger seal element ~~relative to its supporting~~ longitudinally along the outer wall surface;

the outer periphery of the plunger back end portion being receivable into the back of the hollow syringe body upon retraction.

46. (previously presented): The assembly of claim 45 wherein the continuous retaining member acts as a fixed seal for a variable chamber in the barrel behind the continuous retaining member.

47. (currently amended): The assembly of claim 46 wherein a structure mounted in the front end portion of the barrel prevents forward motion of the retractable needle during retraction of the retractable needle to prevent pain when the retractable needle is retracted from a patient.

48. (original): The assembly of claim 45 wherein the continuous retaining member is separable from the retractable needle when retraction is initiated by pushing the plunger to move it forward with respect to the barrel.

49. (previously presented): The assembly of claim 48 wherein the plunger carries a tip which protrudes to contact the continuous retaining member and release the retractable needle when retraction is initiated by pushing on the plunger.

50. (previously presented): The assembly of claim 49 wherein the continuous retaining member is separated from the retractable needle by means of force applied by said tip to said continuous retaining member when retraction is initiated by pushing on said plunger.

51. (canceled)

52. (previously presented): The assembly of claim 45 wherein the outer periphery of the plunger back end portion is lodged in the back of the hollow syringe body by pressing the plunger end to cause retraction, whereby the plunger cannot be grasped after retraction.

53. (canceled)

54. (previously presented): A syringe assembly having a retractable needle and designed for one-time use, comprising:

a front end retraction mechanism having a retractable needle, a needle holder, a biasing element and a continuous retaining member;

a plunger having a front end portion comprising a head and ~~a supporting~~ an outer wall surface on the front end portion having a plunger seal element fixed on the ~~supporting~~ outer wall surface;

a rigid plunger seal element stop surface which acts as a plunger seal element stop;

wherein the needle holder has a front portion extending forwardly beyond the biasing element; and

wherein the retraction mechanism is operated by forward movement of the plunger to release the retractable needle for retraction while the plunger seal element

remains fixed to ~~its supporting~~ the outer wall surface.

55. (previously presented): The syringe assembly of claim 54 wherein the plunger operates the retraction mechanism by acting on the continuous retaining member to release the retractable needle for retraction while the plunger seal element remains fixed to ~~its supporting~~ the outer wall surface.

56. (previously presented): A syringe assembly having a retractable needle and designed for one-time use, comprising:

a hollow syringe body comprising a barrel having a front end portion containing a retraction mechanism having a retractable needle, a needle holder and a continuous retaining member configured for operation by forward movement of a plunger;

a biasing element mounted in the front of the barrel;

a plunger having a retraction cavity and a front end portion comprising a head having a reduced inside diameter relative to the retraction cavity and ~~a supporting~~ an outer wall surface on the front end portion with a plunger seal element fixed on the ~~supporting~~ outer wall surface, and an end cap with an outer periphery opposite the front end; and

the hollow syringe body further comprising a back end portion having an opening for receiving the outer periphery of the end cap.

57. (previously presented): The assembly of claim 56 wherein the outer periphery of the plunger end cap is lodged in the opening of the back end portion of the hollow syringe body by pressing the end cap to cause retraction, whereby the plunger cannot be grasped after retraction.

58. (currently amended): A syringe having a hollow body with first and second open ends and an inside wall of varying inside diameter extending between the first and second open ends, a needle retraction mechanism insertable into the body through the second open end, a plunger having a forwardly extending plunger head insertable into the body through the second open end behind the needle retraction mechanism, and a needle extending forwardly of the first open end, wherein:

the body comprises a nose adjacent to the first ~~opening~~ open end, a barrel adjacent to the second ~~opening~~ open end, and a transition zone between the nose and barrel;

the needle retraction mechanism is grounded inside the nose and comprises an elongated needle holder and a spring;

the elongated needle holder further comprises a needle holding portion secured in fixed relation to the needle, a reduced diameter portion at one end of the needle holding portion, the reduced diameter portion extending forwardly through the first open end; a head at another end of the needle holding portion opposite the reduced diameter portion; a fluid path extending longitudinally through the needle holder in fluid communication with the needle and with a variable fluid chamber inside the body

between the needle holder and the plunger; and a retainer member having a first annular surface slidably engaging the needle holder head and a second annular surface slidably engaging the inside wall of the body opposite the needle holder head; ~~and~~

the spring is confined prior to retraction inside the nose in an annulus defined by the needle holding portion and a portion of the inside wall opposite the needle holding portion;

the plunger head has a tip aligned to abut against the retainer member and slide the retainer member longitudinally out of engagement with the needle holder head during retraction; and

the plunger comprises a retraction cavity into which part of the retraction mechanism is received during retraction to withdraw the needle into the body through the first ~~opening~~ open end.

59. (previously presented): The syringe of claim 58 wherein the inside diameter of the barrel is larger than the inside diameter of the nose, and the inside diameter of the transition zone tapers inwardly between the barrel and the nose.

60. (previously presented): The syringe of claim 58 further comprising an annular shoulder between the needle holding portion and the reduced diameter portion, the annular shoulder abutting against the inside wall proximal to the first open end to ground the elongated needle holder inside the nose.

61. (currently amended): The syringe of claim 58 wherein the tip of the plunger head defines ~~a third~~ an opening into the retraction cavity.

62. (currently amended): The syringe of claim 61 wherein a resilient dislodgeable stopper is positioned in the ~~third~~ opening into the retraction cavity.

63. (previously presented): The syringe of claim 62 wherein a front portion of the dislodgeable stopper extends forwardly of the tip.

64. (previously presented): The syringe of claim 58 wherein the plunger head further comprises a slidable seal contacting the inside wall of the barrel.

65. (previously presented): The syringe of claim 64 wherein the seal is mounted in a fixed axial position on the plunger.

66. (currently amended): The syringe of claim 58 wherein the plunger further comprises ~~an end cap~~ a rear end portion opposite the plunger head, and a thumb cap at the rear end portion.

67. (currently amended): The syringe of claim 66 wherein the ~~end~~ thumb cap has ~~a fourth~~ an opening.

68. (currently amended): The syringe of claim 67 wherein a ~~plug~~ closure is ~~inserted into~~ installed in the ~~fourth~~ opening and the retraction cavity is vented.

69. (currently amended): The syringe of claim 68 wherein the barrel comprises a collar adjacent to the second ~~opening~~ open end, and the ~~end~~ thumb cap fits closely inside the collar when the plunger is depressed during retraction.

70. (previously presented): The syringe of claim 69 wherein the plunger end cap is lodged in the barrel collar by pressing the plunger to cause retraction, thereby preventing subsequent withdrawal of the plunger from the barrel.

71. (previously presented): The syringe of claim 58 comprising a one-piece barrel.

72. (previously presented): The syringe of claim 58 wherein the retainer member is positioned at the most constricted portion of the transition zone where the nose begins.

73. (previously presented): The syringe of claim 58 wherein the retainer member engages the needle holder head with a holding force which exceeds a retraction force applied to the needle holder head by the spring when the spring is compressed.

74. (previously presented): The syringe of claim 58 wherein the nose comprises an annular space between the inside wall and the spring into which the retainer member is forced upon separation from the needle holder head by the plunger tip during retraction.

75. (previously presented): The syringe of claim 58 wherein the needle is inserted into the reduced diameter portion of the elongated needle holder extending forwardly of the body and is attached to the elongated needle holder.

76. (previously presented): The syringe of claim 58 wherein the inside wall of the nose functions as a spring guide during compression of the spring.

77. (previously presented): The syringe of claim 58 wherein the retainer member has an outside mating surface making a seal with the inside wall.

78. (previously presented): The syringe of claim 58 wherein at least a portion of the retraction mechanism is received into the retraction cavity during retraction.

79. (previously presented): The retraction mechanism of claim 58 wherein the retraction mechanism is releasable by forward movement of the plunger to disengage

the retainer member from the needle holder head without contact between the plunger seal element and the retainer member.

80. (previously presented): The syringe of claim 58 wherein the retainer member acts as a fluid seal for the variable fluid chamber prior to retraction.

81. (currently amended): A syringe having a hollow body with first and second open ends and an inside wall of varying inside diameter extending between the first and second open ends, a needle retraction mechanism insertable into the body, a plunger having a forwardly extending plunger head insertable into the body through the second open end, and a needle extending forwardly of the first open end, wherein:

the body comprises a nose adjacent to the first opening, a barrel adjacent to the second opening, and a transition zone between the nose and barrel;

the needle retraction mechanism is grounded inside the nose and comprises an elongated needle holder and a spring;

the elongated needle holder further comprises a needle holding portion secured in fixed relation to the needle and a head opposite the needle holding portion, the needle holding portion extending forwardly through the first open end; a fluid path extending longitudinally through the needle holder in fluid communication with the needle and with a variable fluid chamber inside the body between the needle holder and the plunger; and a retainer member holding the spring in compression inside the nose prior to retraction; ~~and~~

a forwardly extending portion of the compressed spring is confined in an annulus defined by the needle holder and a portion of the body opposite the needle holder;

the plunger head comprises a slidable barrel seal mounted in fixed axial relation to the plunger;

the plunger head abuts against the retainer member following injection and comprises an axially slidable structure that disengages the retainer member from the head of the needle holder during retraction;

the plunger comprises a retraction cavity into which part of the retraction mechanism is received during retraction to withdraw the needle into the body through the first opening; and

the plunger comprises an end cap having an outer periphery, the outer periphery being receivable into the body during retraction to prevent reuse of the syringe.

82. (previously presented): The syringe of claim 81 wherein the inside diameter of the barrel is larger than the inside diameter of the nose, and the inside diameter of the transition zone tapers inwardly between the barrel and the nose.

83. (previously presented): The syringe of claim 81 wherein the barrel comprises a collar adjacent to the second opening, and the end cap has an outer periphery that fits closely inside the collar when the plunger is depressed during retraction.

84. (previously presented): The syringe of claim 81 wherein the retainer member is positioned at the most constricted portion of the transition zone where the nose begins.

85. (previously presented): The syringe of claim 81 wherein the retainer member engages the needle holder head with a holding force which exceeds a retraction force applied to the needle holder head by the spring when the spring is compressed.

86. (previously presented): The syringe of claim 81 wherein the needle is inserted into the needle holder through a portion extending forwardly of the body.

87. (previously presented): The syringe of claim 86 wherein the needle is attached to the needle holder.

88. (previously presented): The syringe of claim 81 comprising a one-piece body.

89. (previously presented): The syringe of claim 81 wherein the inside wall of the nose functions as a spring guide during compression of the spring.

90. (previously presented): The syringe of claim 81 wherein the retainer member has an outside mating surface making a seal with the inside wall.

91. (previously presented): The syringe of claim 81 wherein at least a portion of the retraction mechanism is received into the retraction cavity during retraction.

92. (previously presented): The syringe of claim 81 wherein the retainer member acts as a fluid seal for the variable fluid chamber prior to retraction.

93. (previously presented) The syringe of claim 83 wherein the outer periphery of the plunger end cap is lodged in the barrel collar by pressing the plunger to cause retraction, thereby preventing subsequent withdrawal of the plunger from the barrel.

94. (previously presented): The syringe of claim 81 wherein the plunger comprises a tip that extends forwardly of the plunger seal to initiate retraction.

95. (canceled)

96. (previously presented): A syringe assembly having a hollow body with an inside wall, a retractable needle, a needle retraction assembly seated inside the body and a plunger slidably engaging a portion of the inside wall,

the retraction assembly comprising a compressible spring, a needle holder and a

retainer member continuously surrounding the needle holder to hold the spring in compression prior to retraction, the inside wall and needle holder cooperating as a spring guide during compression of the spring,

the plunger comprising a handle with a longitudinally extending retraction cavity having a first inside diameter and a forwardly extending tip having a second inside diameter less than the first inside diameter, the tip defining an opening through which the needle holder is receivable into the retraction cavity during retraction; a seal disposed in fixed longitudinal relation to the plunger handle and in sliding engagement with the inside wall of the body,

the body further comprising a rigid plunger seal stop surface which acts as a plunger seal stop to limit forward movement of the plunger inside the body.

Claims 97 – 101 **(Canceled)**

Remarks

The Specification

The Cross Reference to Related Applications is amended to insert the number of U.S. 6,090,077, which issued subsequent to filing this application. The paragraph beginning at page 9, line 20, of the specification is amended to correct an apparent transcription error in the text as originally filed. The word "with" was apparently transcribed in place of "which" in the original text, but it appears that substitution of "that" for "which" is more grammatically correct.

In the pending action, Examiner objects to the specification as failing to provide proper antecedent basis for language appearing in certain claims. More specifically, Examiner has required correction of the specification with respect to use of "a rigid plunger seal element stop surface" in claim 54 and with respect to use of "a third opening" in claims 61 and 62.

Regarding claim 54, Applicant respectfully directs Examiner's attention to page 2 of the Amendment and Response to Office Action filed by Certificate of Mailing on November 1, 2002, where the paragraph of the specification originally beginning at page 13, line 7, was amended to read as follows [emphasis supplied]:

> A plunger generally designated by the reference numeral 32 is disposed for use partially within barrel 14. The plunger has a head and seal generally referred to by reference numeral 34, in slidable sealed contact with the interior of barrel 14 of outer body 12. The plunger has a seal element 36 that is conventional and a retraction cavity 38 therein. Plunger seal element 36 fits in supporting surface 35 of the outer surface of head 34. Supporting surface 35 securely holds plunger seal element 36 in position and prevents plunger seal element 36 from longitudinal movement. **The inside wall of the transition zone 18 forms a rigid plunger seal element stop surface 37, which acts as a plunger seal element stop upon forward movement of plunger 32.**

This amendment as previously made was based upon disclosure appearing in the specification, drawings and claims as filed, and is believed to obviate Examiner's instant objection to the specification and corresponding requirement for correction.

Reconsideration and withdrawal of the objection and requirement as applied to claim 54 are therefore requested.

Regarding claims 61 and 62, the objection to the specification is believed to be overcome by the amendments to those claims as presented herein, which now recite an "opening into the retraction cavity" rather than "a third opening" as previously stated. Antecedent basis for "opening into the retraction cavity" appears, for example, in the sentence appearing at page 13, line 11, of the specification as originally filed, which states as follows: "Head 34 has a tip portion 40 forming an opening 41 into the retraction cavity 38." In view of these amendments to claims 61 and 62, reconsideration and withdrawal of the objection to the specification and the associated requirement for correction are respectfully requested.

Claim Objections

Claims 29, 37 and 39 are amended as required.

Regarding claim 45 it appears that the first line of text on page 8 of the Response to Non-Final Office Action (filed by certificate of mailing dated March 10, 2006) was dropped by the printer due to some electronic glitch when printing the copy filed in the PTO, and the undersigned apologizes for not realizing the error in the printed document prior to filing of the response. The text "**retractable, a continuous retaining member which holds the needle, and a back end**" appears as the first line on page 8 of our electronically stored copy of the same document (DALLAS: 75329.77432: 1478557v1). Part of the accidentally omitted text was the antecedent "a continuous retaining member," which led to the objections regarding claims 45-46 and 48-50 on that basis. The accidentally omitted text was previously presented *verbatim* in claim 45 of the Amendment and Response to Restriction Requirement filed by certificate of mailing dated April 10, 2002

The inadvertently dropped text is amended on reinsertion by substituting "retains" in place of "holds" and adding "prior to retraction" after "retractable needle" in the same clause. Claim 45 is also amended to delete "having a retractable needle and" from the

preamble as redundant in view of the recitation of "the retraction mechanism having a retractable needle" in the first subparagraph of claim 45. Taken together, these two amendments avoid any possible confusion regarding reference to two different needles.

Finally, the third objection to claim 45 is obviated by the deletion of "retractable needle" from the phrase "retractable needle retraction mechanism" in the first line of the next-to-last subparagraph of claim 45.

With the correction of claim 45 to reinsert the antecedent "a continuous retaining member," the objections to claims 46 and 48-50 as lacking antecedent basis for "the continuous retaining member" are now moot, and reconsideration and withdrawal of the those objections as to that claim recitation are respectfully requested.

Claim 47 is amended to recite "the retractable needle" in each instance.

With the amendment of claim 45, the objections to claims 48-50 based upon recitation of "the retractable needle" are now moot, and reconsideration and withdrawal of these objections are respectfully requested.

Claim 58, previously allowed, is amended in three places to correct "opening" to "open end" and thereby correspond respectively to the antecedent first and second open ends already recited in the claim. Claim 58 is also amended to delete "and" in line 19 as required.

Claims 61 and 62, which depend from claim 58, are amended for reasons discussed above in Applicant's remarks regarding the specification, and the amendments are well supported, for example, by disclosure appearing at page 13, line 11, of the specification. As amended herein, claims 61 and 62 are believed to satisfy the objection of record.

Claim 67 is amended to recite "an" opening instead of "a fourth" opening. The recitation of "an opening" is supported, for example, at page 29, lines 15-20, of the specification and is appropriate because neither of claims 58 (as amended herein) nor 66 recites an "opening."

Claim 69 is amended to recite the second "open end" instead of second "opening," which is appropriate because the "second open end" to which claim 69 refers has as its antecedent the second open end of claim 58.

Claim 81 is amended to delete "and" in line 16 as required.

Other Amendments to the Claims

Claim 29 is further amended to better distinguish the recited invention over the structural elements disclosed in U.S. 5,019,044 to Tsao, as discussed below in relation to the rejection under § 103(a). Support for the amended language in the first two subparagraphs of claim 29 is found, for example, at page 14, lines 7-15, and at page 15, lines 1-8, of the specification. The next-to-last subparagraph of claim 29 is also amended and is supported, for example, by disclosure appearing at page 17, lines 17-18, at page 20, lines 16-18, and at page 28, lines 1-3. Amendments similar to the amendments to the next-to-last subparagraph of claim 29 are also presented in the next-to-last subparagraphs of claims 37, 45 and 56, in the second and last subparagraphs of claim 54, and in dependent claim 55.

Claims 33 and 34 is amended to recite "inner head of the needle holder" instead of "retractable needle" as supported, for example, by disclosure appearing at page 18, lines 8-17, of the specification. The antecedent for "inner head of the needle holder" appears in amended claim 29, from which claims 33 and 34 indirectly depend.

Claim 37 is also amended to recite a continuous retaining member that "retains" rather than "holds" the retractable needle "prior to retraction" because the retractable needle is retained or held back against the retraction force of the biasing element by the continuous retaining member.

Claims 40 and 42 are amended to substitute "releases" for "is separable from" and "is separated from," respectively. This will make the recitation of claims 40 and 42 more consistent with claim 41, which already recites ". . . to contact the continuous retaining member and release the retractable needle. . . . "

Claim 45, first subparagraph, is amended similarly to the corresponding subparagraph of claim 37. Claim 45, second subparagraph, is amended similarly to the second subparagraph of claim 29. Claim 45, fifth subparagraph, is amended similarly to the fifth subparagraph of claim 29.

In considering the objections to claims 67 and 69, which together with claim 68 depend directly or indirectly from claim 66, which in turn depends from claim 58, it appears that claims 66-69 are better supported by the disclosure appearing, for example, at pages 29-31 of the specification (beginning at page 29, line 15) if they are also amended as shown. These additional amendments include recitation of "a rear end portion," the substitution of "thumb" cap for "end" cap, the substitution of "closure" for "plug" and the recitation of "vented" (the antecedent for "the retraction cavity" being found in the last subparagraph of claim 58). Entry of the additional amendments as shown into the previously allowed claims 66-69 is therefore respectfully requested.

With the amendments to the specification and claims as presented above, all claims pending in the application are believed to be in allowable form and supported by the specification.

The Rejection Under 35 U.S.C. § 103

Claims 29-34, 36-42, 44-50, 52, 54-57 and 96 are rejected under 103(a) as being unpatentable over U.S. 5,019,044 to Tsao ("Tsao") in view of U.S. 5,304,138 to Mercado ("Mercado"), both of which were cited by Applicant. Applicant respectfully traverses the rejection and requests reconsideration and withdrawal based upon the amendments to the claims and the arguments presented below.

Tsao discloses structure that is inoperative for the stated purposes, and Examiner's reliance on both Tsao and the combination of Tsao with Mercado is therefore misplaced and legally insupportable. Because the two L-shaped clamping elements 24, 26 of Tsao are diametrically opposed and do not extend circumferentially around holder plate 34 (see FIG. 1), any medicine drawn into the syringe will flow downwardly around clamping elements 24, 26 and holder plate 34 into the annular

space surrounding spring means 38 and needle 30. Contact between the medicine and spring is undesirable because of possible chemical interaction between the medicine and the metal used to make the spring. Also, the medicine is likely to leak out the front of the syringe because Tsao provides no means for sealing around the needle. In the unlikely event that a fluid-tight interference fit is provided between needle 30 and "structure 18" (which is not even referenced in the text of the specification) or between needle 30 and the front of cylindrical front half portion of clamping means 20 (col. 2, lines 53-55), then needle 30 would be held by the frictional engagement with those structures and needle 30 would likely not release for retraction even when L-shaped clamping elements 24, 26 are forced away from engagement with holder plate 34.

Perhaps more importantly, air leakage around needle 30 where it passes through structure 18 and the front of clamping means 20 will reduce the ability of plunger 22 to draw a vacuum inside the syringe when drawing medicine from a vial, and will cause excess air and air-borne impurities and pathogens to be drawn into the syringe prior to injection. This important aspect of syringe construction is disclosed by Applicant at, for example, page 32, lines 12-14, of the instant specification and is not addressed by Tsao. In Applicant's device, the continuous retaining member forms a fluid seal with the inside of the syringe body that prevents medicine from contacting the spring or from leaking out the front of the syringe.

Mercado appears to be operative, but discloses two embodiments, both of which require the simultaneous use, in combination with the "countersunk" barrel portion, of either: (1) a frangible boss 28 on the front end of plunger 22, which boss functions in cooperation with circumferential lip 34 to destroy boss 28 if plunger 22 is again withdrawn for reuse (Col. 2, lines 40-51); or (2) the combination of outwardly directed flange 48 on the internal surface of recess 46 with inwardly directed flange 52 of peripheral skirt 50, which locks the plunger into the barrel and prevents further use of the syringe (Col. 3, lines 14-24). The first embodiment disclosed by Mercado cannot even be used in the syringe of Tsao because of the requirement for a frangible boss that is not adapted for use with a plunger containing a retraction cavity. As to the

second embodiment, Tsao already discloses wedge rings 11 and 59 at the rear opening of the barrel that lock the plunger in its fully depressed position following retraction. Applicant addresses the undesirability of "locking teeth" to lock the plunger after retraction at page 34, line 20 through page 35, line 7, of the instant specification.

In addition to the facts that the syringe of Tsao is inoperative as disclosed and that the teachings of Mercado require either a frangible boss unusable with the Tsao syringe or a locking structure taught to be undesirable by Applicant, there is no suggestion in either Tsao or Mercado that would lead one of ordinary skill in the art to combine their teachings. The combination of Tsao with Mercado is, therefore, legally insufficient to establish a *prima facie* case of obviousness. Beyond that, neither Tsao nor Mercado discloses elements as recited in each of the rejected claims.

As amended herein, claim 29 recites a "needle holder having an inner head and a continuous retaining member. . . ." The continuous retaining member is now recited to be "surrounding the inner head of the needle holder and having a surface mating with a facing surface of the body." Tsao does not disclose a continuous retaining member surrounding the head of the needle holder and does not disclose a needle holder having a surface mating with a facing surface of the body. Tsao discloses the use of clamping means 20 having an externally threaded cylindrical section seated in the nose and two diametrically opposed L-shaped clamping elements 24 and 26 that support and restrain the needle holder plate 34. Claim 29 also recites "a plunger seal element fixed on an outer wall surface" that is not disclosed by Tsao. As disclosed by Applicant at, for example, page 28, lines 1-3 and in FIG. of the specification, "Plunger seal 36' fits in a depression in the outer surface of wall 140 where it is securely held in position and prevented from longitudinal movement." Referring to FIG. 1 of Tsao, it is apparent that the ring-shaped plunger seal element 60 of Tsao does not fit in a depression in the outer surface of plunger 50 and can slide longitudinally along the plunger, particularly when seal element 60 passes wedge ring 11 during assembly. Mercado does not even disclose a needle retraction mechanism, and does not remedy the deficiencies of Tsao.

These remarks likewise apply to the similar amendment of claims 37, 45 and 54-56 regarding the recited structure.

Claims 30-34 and 36 depend from claim 29 and are similarly distinguishable over Tsao and Mercado for at least the foregoing reasons. Additional reasons are set forth below.

As to claim 30, Examiner states that Tsao discloses "a structure in the front end portion 18," citing to FIGS. 1-4. The structure to which Examiner refers appears to be the front of barrel 12, although reference numeral 18 does not appear in the specification of Tsao. However, claim 30 further recites that said structure "prevents forward motion of the retractable needle during retraction of the needle. . . ." Tsao's device does not. In Applicant's device, a lower portion of the needle holder prevents forward motion of the retractable needle in response to a force exerted by the advancing plunger because the needle holder engages and abuts against the front of the syringe body. Conversely, with the device of Tsao, the application of force to plate holder 34 will cause the needle to push forward by further compressing, jamming or buckling the spring. This is contrary to the teachings of Applicant at, for example, page 15, lines 10-12, of the instant specification. When, as is preferred, the needle is retracted following injection and prior to otherwise withdrawing the needle from the patient to avoid possible transfer of blood or accidental needle stick to the user, forward movement of the needle causes pain to the patient and is desirably avoided. Furthermore, the permitted manufacturing tolerance in the spring length must then also be taken into consideration as part of the permitted needle length.

Claim 31 recites the elements of claim 29 in combination with a plunger tip which protrudes to contact the continuous retaining member. Neither Tsao nor Mercado discloses a continuous retaining member surrounding the inner head of the needle holder.

Claim 32 recites the elements of claim 29 in combination with a continuous retaining member that is a separable part of the retraction mechanism which acts as a fluid seal for a variable chamber in the barrel behind the separable part. Neither Tsao

nor Mercado discloses either the elements of claim 29 or the additional fluid seal aspect of the continuous retaining member as recited in claim 32.

Claims 33 and 34 recite the elements of claim 29 in combination with a continuous retaining member that is separable from the inner head of the needle holder when retraction is initiated by pushing on the plunger. Neither Tsao nor Mercado discloses a continuous retaining member surrounding the inner head of the needle holder.

Claim 36 recites the elements of claim 29 in combination with a plunger end cap lodged in the opening of the back end portion of the hollow syringe body by pressing the end cap to cause retraction. Tsao does not disclose lodging the plunger end cap in an opening and Mercado does not disclose such lodging except in combination with either a frangible boss or locking flanges, and even then, not by pressing the end cap to cause retraction. Mercado does not even disclose a plunger into which a needle can be retracted. One attempting to use the disclosure of Tsao would not be led to incorporate the lodging concept of Mercado because Tsao already comprises wedge rings 11, 59 disposed near the opening that lock the plunger in a depressed position as shown in FIG. 4 after wedge ring 59 slides past wedge ring 11 when the plunger is fully depressed to retract the needle. Mercado therefore fails to remedy the deficiencies of Tsao.

As amended, claim 37 also recites that the retractable needle is retained prior to retraction by a continuous retaining member that is not present in Tsao or in Mercado. Claim 37 further recites that the retraction mechanism is operable by forward movement of the plunger without distorting the barrel. Comparing FIGS. 3 and 4 of Tsao, it is apparent that the rear portion of the barrel of Tsao must be distorted outwardly to initiate retraction because wedge ring 59 must be forced past wedge ring 11 to reach the position of FIG. 4, thereby distorting the barrel and undesirably increasing the thumb force that must be applied to enclosed handle portion 58. Claim 37 also recites that the outer periphery of the plunger end cap is receivable into the opening in the back end portion of the hollow syringe body upon retraction, which is not disclosed by Tsao

because Tsao uses locking wedge rings 11, 59 to prevent withdrawal of the plunger from the barrel. Claim 37 also recites "a plunger seal element fixed on an outer wall surface" that is not disclosed by Tsao, as discussed above in relation to claim 29. Mercado does not disclose retraction and requires the use of either a frangible boss on the head of the plunger or locking flanges inside the recess at the rear of the barrel. Mercado, therefore, fails to remedy the other deficiencies of the retraction mechanism and plunger disclosed by Tsao.

Claim 38 recites the elements of claim 37 in combination with a continuous retaining member that acts as a fixed seal for a variable chamber in the barrel behind the continuous retaining member. As discussed above, the L-shaped clamping elements 24, 26 of Tsao do not act as a fixed seal for a variable chamber in the barrel behind the continuous retaining member, and Mercado does not even disclose a retraction mechanism.

Claim 39 recites the elements of claim 37 in combination with a structure mounted in the front end portion of the barrel that prevents forward motion of the retractable needle during retraction to prevent pain when the retractable needle is retracted from a patient. Applicant's comments above in relation to claim 30 are also applicable here.

Claims 40-42 and 44 recite the elements of claim 37 in combination with other recitations that generally parallel those of claims 33, 31, 34 and 36, respectively, and are likewise believed to patentably distinguish over Tsao and Mercado for reasons discussed above.

As amended, Claim 45 recites a syringe assembly comprising: a hollow syringe body with a retraction mechanism having, *inter alia*, a continuous retaining member that retains the retractable needle prior to injection, the continuous retaining member having a surface mating with a facing surface of the hollow syringe body, thereby making a seal for a variable fluid chamber in the barrel; a plunger seal element fixed on the supporting surface; and the outer periphery of the plunger back end portion being receivable into the back of the hollow syringe body upon retraction. Tsao fails to disclose the retraction

mechanism having the elements recited above, a plunger seal element fixed on an outer wall surface, and a plunger back end portion that is receivable into the back of the hollow syringe body upon retraction. Mercado requires the use of either a frangible boss on the head of the plunger or locking flanges inside the recess at the rear of the barrel. Mercado fails to disclose a syringe having a retraction mechanism, requires the use of either a frangible boss on the head of the plunger or locking flanges inside the recess at the rear of the barrel, and also fails to remedy the other deficiencies of the retraction mechanism and plunger disclosed by Tsao.

Claims 46-50 and 52 recite the elements of claim 45 in combination with other recitations that generally parallel those of dependent claims 32 and 38, 30 and 39, 33 and 40, 31 and 41, 34 and 42, and 36 and 44, respectively, and are likewise believed to patentably distinguish over Tsao and Mercado for reasons discussed above.

Claim 54 recites a syringe assembly comprising, *inter alia*, a retraction mechanism with a continuous retaining member, a plunger having a plunger seal element fixed on an outer wall surface, a rigid plunger seal element stop surface which acts as a plunger seal element stop, and a needle holder with a front portion extending forwardly beyond the biasing element. Tsao fails to disclose either the needle holder with a front portion extending forwardly beyond the biasing element or a combination of other features disclosed above. Mercado fails to remedy the deficiencies of Tsao.

Claim 55 recites the elements of claim 54 in combination with a plunger that operates the retraction mechanism by acting on the continuous retaining member that Tsao fails to disclose. Mercado fails to disclose a retraction mechanism.

Claim 56 recites a syringe assembly comprising, *inter alia*, a retraction mechanism having a continuous retaining member, a plunger seal element fixed on an outer wall surface, and an opening at the back end portion of the syringe body to receive the outer periphery of the plunger end cap. Tsao fails to disclose the combination of elements recited above for reasons previously discussed. Mercado fails to disclose a retraction mechanism, requires the use of either a frangible boss on the head of the plunger or locking flanges inside the recess at the rear of the barrel, and

also fails to remedy the other deficiencies of the retraction mechanism and plunger disclosed by Tsao.

Claim 96 recites a syringe assembly having, *inter alia*, a needle retraction assembly comprising a compressible spring, a needle holder, a retainer member continuously surrounding the needle holder to hold the spring in compression prior to retraction, the inside wall and needle holder cooperating as a spring guide during compression of the spring, and a plunger seal disposed in fixed longitudinal relation to the plunger handle. Referring, for example, to FIG. 2 of Tsao, Tsao discloses significant lateral space on both sides of spring means 38. By contrast, with reference, for example, to FIGS. 1 and 2 of the instant application, a major portion of the length of Applicant's spring is closely confined between the inside wall of the syringe body and the needle holder. This difference is especially significant during assembly of the syringe, when the spring is being compressed. This feature as recited in claim 96 is described by Applicant, for example, at page 34, lines 5-12 of the specification. Tsao does not disclose any appreciation of this problem and its solution as disclosed by Applicant. Mercado does not remedy this deficiency of Tsao because Mercado fails to disclose a retraction mechanism. Both Tsao and Mercado also fail to disclose a retainer member continuously surrounding the needle holder to hold the spring in compression prior to retraction. Tsao also fails to disclose a plunger seal disposed in fixed longitudinal relation to the plunger handle, and Mercado fails to disclose a plunger having a retraction cavity.

In view of the foregoing amendments and Remarks, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) are respectfully requested.

Conclusion

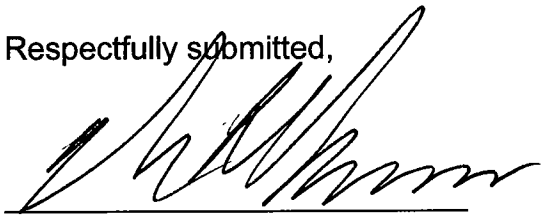
Claims 58-94 are already allowed. To the extent that Applicant's Remarks presented herein also have applicability to patentability of the subject matter of the previously allowed claims, Applicant relies upon these Remarks and upon the remarks

made previously during prosecution of these claims as supplementing the statement of reasons for allowance as presented in paragraph 5 of the instant action.

As presented herein, claims 29-34, 36-42, 44-50, 52, 54-57 and 96 are believed to be fully supported by the specification, and are also believed to be in condition for allowance and to patentably distinguish over the cited art. Applicant therefore asks that all pending claims be passed to issue without delay. If there is any remaining issue regarding allowability of all claims, please contact the undersigned by telephone so that we may confer regarding any remaining issue, or preferably, schedule a personal interview.

Although no fee is believed to be required for filing this response, please charge any additional fee that may be required or credit any overpayment to Deposit Account No. 12-1781 of Locke Liddell & Sapp, LLP.

Respectfully submitted,



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